FEB 5 2013

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510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Z Classic Stems.

(a)(1) Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002 (800) 238-7188
Date:	November 5, 2012
Contact Person:	David Fitch, PhD *Clinical Affairs Specialist*
(a)(2) Proprietary Name of Modified Device:	PROFEMUR® Z Classic Stems
Common Name:	Femoral Hip Stem
Classification Name and Reference:	888.3350 JDI Hip joint metal/polymer semi-constrained cemented prosthesis Class II 888.3353 LZO Hip joint metal/ceramic/polymer, cemented or non-porous, uncemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/JDI/LZO
(a)(3) Predicate Devices:	PROFEMUR® Z Plasma-Coated Hip Stem, K111699 STEM Hip Replacement System, K021346

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(a)(4) Device Description
The purpose of this submission is to add a monolithic femoral neck option to the PROFEMUR® Z Hip System. The PROFEMUR® Z Classic Stems are monolithic stems manufactured from a forged titanium alloy (ASTM F620) and designed for use in uncemented total hip arthroplasty. The PROFEMUR® Z Classic Stems are available in 9 sizes (1-9) and are available in two surface finish options: gritblast or titanium plasma spray conforming to ASTM F1580. Each size is available with either a long or short fixed femoral neck and all sizes are available in two neck offset options, Standard (neutral) and Extended (varus). The surface finish options, neck lengths, and neck offset are designed to create options identical to those available with the predicate modular devices.

(a)(5) Indications for Use
The PROFEMUR® Z Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Z Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

(a)(6) Technological Characteristics of the Device
The indications for use of the PROFEMUR® Z Classic Stems are identical to those for the predicate devices (K111699, K021346). The subject devices are made from an identical titanium alloy (ASTM F620) as the predicate devices. The PROFEMUR® Z Classic Stems are designed to provide identical range of sizes, surface finishes, neck lengths, and neck offsets as those provided by the modular predicates. The subject device design is identical to that of the predicate devices with the exception of featuring a monolithic neck design and a slightly modified impaction slot.

(b)(1) Nonclinical Testing
The PROFEMUR® Z Classic Stems were evaluated in proximal and distal fatigue tests in accordance with ISO 7206-4, 6, and 8 and satisfied the acceptance criteria of each. Range of motion was evaluated in accordance with ISO 21535 and the subject device satisfied the acceptance criteria. The titanium plasma spray coating is applied according to WMT specification and is identical to that used in the predicate device (K111699). The titanium plasma spray coating was verified by testing present within a vendor Master File and summarized within this premarket notification.

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(b)(2) Clinical Testing
Clinical data was not provided for the subject devices.

(b)(3) Conclusions
The indications for use and fundamental scientific technology of the PROFEMUR® Z Classic Stems are identical to those of the predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The safety and effectiveness of the PROFEMUR® Z Classic Stems is adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Incorporated
% David Fitch, Ph.D.
Clinical Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Letter dated: February 5, 2013

Re: K123434
Trade/Device Name: PROFEMUR® Z Classic Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI
Dated: January 7, 2013
Received: January 8, 2013

Dear Dr. Fitch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123434

Device Name: PROFEMUR® Z Classic Stems

Indications for Use:

The PROFEMUR® Z Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
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The PROFEMUR® Z Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
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Division of Orthopedic Devices